REMARKS

Applicants respectfully request reconsideration of the present application. No new matter has been added to the present application. Claims 1-51 have been rejected in the Office Action. Claim 1 has been amended, no new claims have been added, and no claims have been canceled in this Amendment. Accordingly, claims 1-51 are pending herein. Claims 1-51 are believed to be in condition for allowance and such favorable action is respectfully requested.

Objections to the Claims

Claim 1 was objected to in the Office Action as the claim inadvertently references "the second medication" as opposed to "the selected medication." Applicants thank the Examiner for noting this error. An amendment to claim 1 has been submitted herein to correct this inadvertent error. Because the amendment introduces no new matter and places the claim in better form for consideration on appeal, Applicants respectfully request that the amendment be entered pursuant to 37 C.F.R. § 1.116.

Rejections based on 35 U.S.C. § 103

A. Applicable Authority

Title 35 U.S.C. § 103(a) declares, a patent shall not issue when "the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." The Supreme Court in *Graham v. John Deere* counseled that an obviousness determination is made by identifying: the scope and content of the prior art; the level of ordinary skill in the prior art; the differences between the claimed invention and prior art references; and secondary considerations. *Graham v. John Deere Co.*, 383 U.S. 1 (1966).

To support a finding of obviousness, the initial burden is on the Office to apply the framework outlined in *Graham* and to provide some reason, or suggestions or motivations found either in the prior art references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the prior art reference or to combine prior art reference teachings to produce the claimed invention. See, *Application of Bergel,* 292 F. 2d 955, 956-957 (1961). Thus, in order "[t]o establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success [in combining the references]. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations." *See* MPEP § 2143. Recently, the Supreme Court elaborated, at pages 13-14 of *KSR*, it will be necessary for [the Office] to look at interrelated teachings of multiple [prior art references]; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by [one of] ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the [patent application]." *KSR v. Teleflex*, 127 S. Ct. 1727 (2007).

B. Rejections based on Engelson and Lambert

Claims 1-51 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,671,563 to Engelson et al. (the "Engelson reference) and U.S. Patent No. 6,529,892 to Lambert (the "Lambert reference"). As the Engelson and Lambert references, either alone or in combination, fail to teach or suggest all claim limitations of claims 1-51, Applicants respectfully traverse this rejection, as hereinafter set forth.

Referring initially to claim 1, as noted in the previous response, the claim is directed to providing medication administration errors by providing medication administrations comments at a place of administration of a medication. A given medication may be associated with multiple compliance rules that each correspond with a different condition and different medication administration comment. When a condition for a given compliance rule is satisfied, the medication administration comment for that compliance rule is displayed. Neither the Engelson reference nor the Lambert reference contemplate having multiple different compliance rules associated with a given medication and providing a medication administration comment from one of the compliance rules when the condition for that compliance rule has been satisfied.

As described in the Specification of the present application, embodiments of the invention may go beyond providing compliance for the traditional five patient rights by also checking for "compliance with many additional specified conditions." *See, Specification*, p. 14, lines 16-23. Accordingly, multiple compliance rules may be associated with a single medication. *See, e.g., id.*, p. 15, lines 13-14. Each compliance rule for a given medication may have a different condition for triggering the compliance rule and a different medication administration comment that is displayed when the corresponding condition is satisfied. *See, e.g., id.*, p. 15, lines 3-22. In other words, the condition and comment of one compliance rule for a given medication differs from the condition and comment of another compliance rule for that given medication. Accordingly, a variety of different medication administration comments may be displayed at the time of administration depending upon the conditions that are present. *See, e.g., id.*, p. 15, lines 3-11.

In contrast to the invention of claim 1, the Engelson reference discusses providing discrepancy checking. *See, e.g., Engelson*, col. 13, 49-59. In particular, a bar code associated

with a patient is scanned to identify the patient to the system, and a bar code associated with a medication to be administered is scanned to identify the medication to the system. *See, e.g., id.*, col. 13, lines 24-31. The system then checks the patient's medication administration record to verify whether the identified medication is scheduled to be administered to the identified patient. *See, e.g., id.*, col. 13, lines 49-59. If there is a discrepancy (i.e., the medication and patient don't match in the medication administration record), a warning is provided. *Id.*

At best, the discrepancy checking aspect of the Engelson reference is a single compliance rule for a given medication. However, the Engelson reference fails to discuss having two or more compliance rules for a given medication, in which each compliance rule has its own condition and own medication administration comments. As such, the Engelson reference fails to teach or suggest multiple limitations of independent claim 1, as amended herein.

The differences between the approach in the Engelson reference and the invention of claim 1 are significant. Instead of only providing discrepancy checking as in the Engelson reference, the invention of claim 1 includes providing two or more compliance rules for a single medication such that a variety of different medication administration comments may be provided when a medication is to be administered dependent upon what conditions are satisfied. As such, the invention of claim 1 provides a substantial advantage over Engelson's discrepancy checking. For instance, one medication administration comment may be provided when a particular condition is satisfied while a different medication administration comment may be provided when a different condition is satisfied. In some cases, multiple compliance rules may be triggered by various different conditions and the corresponding medication administration comments may be provided. By contrast, Engelson's discrepancy checking is less effective as it only provides a determination of whether the medication is indicated in the patient's medication

administration record. Accordingly, the invention of claim 1 advances the state of the art beyond what is discussed in the Engelson reference.

The Office Action recognizes that the Engelson reference fails to teach or suggest multiple limitations of claim 1, but asserts that the differences between the Engelson reference would have been obvious to one skilled in the art in view of the Lambert reference. *See* Office Action p. 3-4. Applicants respectfully disagree. In particular, the Lambert reference fails to cure the deficiencies of the Engelson reference, namely providing multiple compliance rules for a given medication, each compliance rule having a corresponding condition and medication administration comment, and providing a medication administration comment for a compliance rule when it is determined that a corresponding condition for that compliance rule has been satisfied.

The Lambert reference fails to teach or suggest these features of claim 1. In contrast to claim 1, the Lambert reference is directed to comparing attributes of drug products to determine a likelihood of confusion between the drug products and, in some instances, a severity of confusion. *See, e.g., Lambert*, Abstract; col. 3, line 55 – col. 4, line 5; col. 5, lines 38-58. The Lambert reference is not concerned with providing medication administration comments at the place of administration of a medication. Instead, the Lambert reference is concerned with determining the likelihood (and severity) that drug products may be confused with one another. There is no indication in the Lambert reference of providing medication administration comments. Additionally, there is no indication in the Lambert reference of providing such medication administration comments based on an associated condition being satisfied. As such, the Lambert reference at least fails to teach or suggest providing multiple compliance rules for a given medication, each compliance rule including a corresponding condition and medication

administration comment, determining that one of the conditions for a compliance rule has been satisfied, and providing a medication administration comment from that compliance rule.

As such, it is respectfully submitted that the Engelson and Lambert references, either alone or in combination, fail to teach or suggest the limitations of independent claim 1, and, as such, claim 1 is patentable over the Engelson and Lambert references. Accordingly, Applicants respectfully request withdrawal of the rejection of independent claim 1 under 35 U.S.C. § 103(a). Independent claim 1 is believed to be in condition for allowance and such favorable action is respectfully requested.

Independent claims 18 and 35 recite some features similar to those discussed above with respect to claim 1. In particular, both independent claims 18 and 35 recite two or more or a plurality of compliances rules corresponding with a single medication. As such, claims 18 and 35 are patentable over the Engelson and Lambert references for at least the above-cited reasons. Accordingly, Applicants respectfully request withdrawal of the rejection of claims 18 and 35 under 35 U.S.C. § 103(a). Claims 18 and 35 are believed to be in condition for allowance and such favorable action is respectfully requested.

Claims 2-17, 19-34, and 36-51 depend directly or indirectly from independent claims 1, 18, and 35. As such, Applicants respectfully request withdrawal of the 35 U.S.C. § 103(a) rejections of these claims as well.

CONCLUSION

Each of claims 1–51 is believed to be in condition for allowance, and a timely notice of allowance is solicited. Should it be determined that additional issues remain which might be resolved by a telephone conference, the Examiner is respectfully invited to contact Applicants' undersigned attorney. No fee is believed due in conjunction with this Amendment. However, if this belief is in error, the Commissioner is hereby authorized to charge any fee which may be required to Deposit Account No. 19-2112.

Respectfully submitted,

/John S. Golian/

John S. Golian
Reg. No. 54,702

SHOOK, HARDY & BACON L.L.P.
2555 Grand Boulevard
Kansas City, MO 64108-2613
816-474-6550